



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,649	02/19/2002	Yun Hwang Choe	213.1077-CTML-U	5287
22856	7590	02/12/2004	EXAMINER	
MUSERLIAN, LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,649

Applicant(s)

CHOE ET AL

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1615

DETAILED ACTION

Receipt of change of address for correspondence and response to election requirement dated 11-3-03 is acknowledged.

Upon reconsideration, examiner has withdrawn the election requirement made in the previous office action. Accordingly, all the pending claims 1-24 have been examined.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/078,730. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and co-pending claims recite a compound wherein one of the variables of D1 and D2 of the instant compound is OH. Accordingly, a compound resulting from instant D1 and D2=OH, is the same as the compound of co-pending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1615

Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 6,180,095 and claims 1-34 of U. S. Patent application No. 6,303,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds recited in the above patents include the claimed compound. Instant claimed compound recite the variable M as O, S or NR₄, which reads on the variable L of the patented claims because L₁ in both patents can be -M-(CR₇R₈)_n, where N=0 or a positive integer. Assuming n=0, then L₁=M. Further, M is defined in both patented claims as X, an electron withdrawing group that includes variable NR₁₂, R₁₂ being a H. Patented claims define Y₃ as O, S or NR₁₂. Substituting Y₃=NR₁₂ in the compounds of the patented claims reads on the NE₄-CE₁, E₂ and E₃. However, the instant variables n and p can be zero. Accordingly, instant NE₄-CE₁, E₂ and E₃ can read on NR₁₂. Both the patented compounds teach the aryl moieties that read on the aryl moieties of the instant variables D₁ and D₂. Thus, instant compounds are obvious from the patented compounds and further, both the instant and the patented compounds are used for the same purposes i.e., prodrug conjugates. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the claimed compounds from the patented compounds and use them as prodrug conjugates with an expectation to obtain high levels of drug transport.

2. Claims 1-24 are directed to an invention not patentably distinct from claims 1-54 of commonly assigned US 6,180,095 ('095). Specifically, as described above the compounds of the instant invention and their preparation is also described in the above patent.

Art Unit: 1615

Claims 1-24 are directed to an invention not patentably distinct from claims 1-34 of commonly assigned US 6,303,569 ('569). Specifically, as described above the compounds of the instant invention and their preparation is also described in the above patent.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned '569 and '095, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

3. Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,638,499 ('499); claims 1-19 of U.S. Patent No. 6,395,266 ('266) and 1-17 of U.S. Patent No. 6,153,655 ('655). Although the conflicting claims are not identical, they are not patentably distinct.

Art Unit: 1615

Claims 1-14 of '499 are directed to a compound that read on the instant claimed compound in particular with the variables E1-4 and B. Instant claimed compound recites variables D1 and D2 are independently OH, formulae IV or V. The compound of '499 contains the formula of at least one of the E1-3 on a variable that reads on D1 or D2. Examiner notes that instant formulae IV and V recite L1 and L2. However, the claim states that subscripts v and t associated with L1 and L2 respectively is zero or a positive integer. Accordingly, if t and v are considered to be zero, then the resulting D1 and D2 read on one of the E1-3 groups in col. 30, lines 5 of '499 patent. The compounds of '499 are used for the same purpose i.e., drug conjugating polymers.

Claims 1-19 of '266 are directed to a compound that read on the instant claimed compound in particular with the variables E1-4 and B. Instant claimed compound recites variables D1 and D2 are independently OH, formulae IV or V. The compound of '266 contains the formula of at least one of the E1-3 on a variable that reads on D1 or D2. Examiner notes that instant formulae IV and V recite L1 and L2. However, the claim states that subscripts v and t associated with L1 and L2 respectively is zero or a positive integer. Accordingly, if t and v are considered to be zero, then the resulting D1 and D2 read on one of the E1-3 groups in col. 31, lines 10 of '266 patent. The compounds of '499 are used for the same purpose i.e., drug conjugating polymers.

Claims 1-17 of patent '655 also describes a compound as a conjugate for drugs that fits the description of the compound of the instant claims. In particular, when the instant variables L1 and L2 are taken as zero, then the instant claimed compound encompasses the compounds of '655 (also see compound of 14).

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the polymers of '499, '266 or '655 that are encompassed by the instant invention claims with an expectation to produce polymers that can be used as drug conjugates for a variety of drugs to be transported.

4. Claims 1-24 are directed to an invention not patentably distinct from claims 1-19 of commonly assigned US 6,395,266. As explained in the previous paragraphs, both the instant application and the patent are directed to polymer drug conjugates for delivering several kinds of drugs.

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 6,395,266, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly

Art Unit: 1615

assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

February 9, 2004